

55 FR 9366

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FEDERAL REGISTER

55 FR 9366

March 13, 1990

National Toxicology Program; Chemicals (8) Nominated for Toxicological Studies; Request for Comments

SUMMARY: On January 24, 1990 the Chemical Evaluation Committee (CEC) of the **National Toxicology Program** (NTP) met to review eight chemicals nominated for in-depth toxicological studies, and to recommend the types of studies to be performed, if any. With this notice, the NTP solicits public comments on the chemicals.

FOR FURTHER INFORMATION CONTACT: Dr. Victor A. Fung, Chemical Selection Coordinator, **National Toxicology Program**, Room 2B55, Building 31, National Institutes of Health, Bethesda, Maryland 20892, (301) 496-3511.

TEXT: SUPPLEMENTARY INFORMATION: As part of the chemical selection process of the National Toxicology Program, nominated chemicals which have been reviewed by the NTP Chemical Evaluation Committee (CEC) are published with request for comment in the Federal Register. The CEC is composed of representatives from the agencies participating in the NTP. This is done to encourage active participation in the NTP chemical evaluation process, thereby helping the NTP to make more informed decisions as to whether to select, defer or reject chemicals for toxicology study. Comments and data submitted in response to this request are reviewed and summarized by NTP technical staff, are forwarded to the NTP Board of Scientific Counselors for use in their evaluation of the nominated chemicals, and then to the NTP Executive Committee for decision-making. The NTP chemical selection process is summarized in the Federal Register, April 14, 1981 (46 FR 21828), and also in the NTP FY 1988 Annual Plan, pages 16-19.

On January 24, 1990, the CEC met to evaluate eight chemicals nominated to the NTP for in-depth toxicological studies. The following table lists the chemicals, their Chemical Abstract Service (CAS) registry numbers, and the types of toxicological studies recommended by the CEC at the meeting.

Chemical	CAS registry No.	Committee recommendations
Bisphenol A diglycidyl ether	1675-54-3	Carcinogenicity studies by industry through EPA test rule.
2-Bromo-2-nitropropane-1,3-diol	51-52-7	No testing.
Cinnamaldehyde	104-55-2	Carcinogenicity.
C.I. Acid Red 97	10169-02-5	Chemical analysis metabolism.
C.I. Acid Red 111	6358-57-2	No testing.
C.I. Basic Brown 1	1052-38-6	Carcinogenicity.
C.I. Basic Brown 2	6358-83-4	No testing.
C.I. Direct Black 80	8003-69-8	Dermal absorption.

Three of the eight chemicals were previously selected for toxicology studies by the NTP. Bisphenol A diglycidyl ether was mutagenic in *Salmonella*, and was positive for chromosomal aberrations and sister chromatid exchanges in Chinese hamster ovary cells in culture. Cinnamaldehyde was weakly positive in *Salmonella*; positive for sex-linked recessive lethal mutations and negative for reciprocal translocations in *Drosophila*; negative for chromosomal aberrations and positive for sister chromatid exchanges in Chinese hamster ovary cells in culture. It is currently on test in the

mouse lymphoma assay. No maternal toxicity or adverse reproductive effects were observed in a short-term *in vivo* reproductive toxicity study of cinnamaldehyde. Acute feeding studies of cinnamaldehyde have been completed. 2-Bromo-2-nitro-propane-1,3-diol is on test in *Salmonella*.

The CEC also reviewed and selected 10% carbamide peroxide in anhydrous glycerine base for mutagenicity studies in *Salmonella*. The CEC serves as the selecting mechanism for the chemicals nominated solely for NTP genotoxicity studies.

Interested parties are requested to submit pertinent information. The following types of data are of particular relevance:

- (1) Modes of production, present production levels, and occupational exposure potential.
- (2) Uses and resulting exposure levels, where known.
- (3) Completed, ongoing and/or planned toxicologic testing in the private sector including detailed experimental protocols and results, in the case of completed studies.
- (4) Results of toxicological studies of structurally related compounds.

Please submit all information in writing by April 12, 1990, to Dr. Fung. Any submissions received after the above date will be accepted and utilized where possible.

Dated: March 6, 1990.

David P. Rall,

Director, National Toxicology Program.

[FR Doc. 90-5688 Filed 3-12-90; 8:45 am]

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